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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

BRENDA PLYLER, Plaintiff, v. BOSTON SCIENTIFIC, CORP., and JOHN DOE CORPORATIONS 1-50 Defendants.	)	Case No.

COMPLAINT

Plaintiff, Brenda Plyler, brings this case against Defendants for injuries suffered as a direct result of Plaintiff's implantation of the Obtryx mesh product. Plaintiff alleges as follows:

THE PARTIES

1. Plaintiff, Brenda Plyler, is a citizen and resident of the state of Alabama.
2. Boston Scientific Corp. ("Boston Scientific") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Massachusetts
3. Defendant John Doe Corporations 1-50 represent presently unknown designers, researchers, developers, manufacturers, marketers, distributors, promoters, suppliers, and sellers of the Boston Scientific Obtryx device, which was and is defective and unreasonably dangerous to women.

JURISDICTION AND VENUE

4. Plaintiff brings this complaint under federal diversity jurisdiction, 28 U.S.C. § 1332, as the parties are completely diverse in citizenship and the amount in controversy exceeds $75,000.

5. Venue is proper under 28 U.S.C. § 1391(b) as a substantial part of the events giving rise to this claim occurred in this district.

FACTUAL ALLEGATIONS

6. Plaintiff was implanted with a BOSTON SCIENTIFIC Obtryx product during surgery performed at St. Vincent's Hospital in Birmingham, Alabama on September 2, 2016.

7. Following the implantation of the Obtryx, Plaintiff experienced painful complications and as a result of those complications, on March 10, 2017, Plaintiff underwent a revision surgery to revise the Obtryx mesh.

8. Defendants, at all times material hereto, manufactured the BOSTON SCIENTIFIC Obtryx product.

9. The BOSTON SCIENTIFIC Obtryx product was implanted in the Plaintiff to treat her for Stress Urinary Incontinence and other symptoms, the use for which the product was designed, marketed and sold.

10. As a result of having the BOSTON SCIENTIFIC Obtryx product implanted in her, Plaintiff has experienced significant mental and physical pain, disability, suffering, has sustained permanent injury, and permanent and substantial physical deformity, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income, and other damages.

11. Plaintiff's injuries would not have occurred but for the defective nature of the product implanted and/or Defendants' wrongful conduct.

12. Defendants at all times material hereto, was engaged in the business of placing medical devices in the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the BOSTON SCIENTIFIC Obtryx product and that which was implanted in the Plaintiff, which gives rise to the Plaintiff's claims asserted herein.
13. Defendants at all times material hereto designed the BOSTON SCIENTIFIC Obtryx product, including that which was implanted in the Plaintiff, which gives rise to the Plaintiff's claims asserted herein.
14. Defendants at all times material hereto manufactured the BOSTON SCIENTIFIC Obtryx product, including that which was implanted in the Plaintiff, which gives rise to the Plaintiff's claims asserted herein.
15. Defendants at all times material hereto marketed the BOSTON SCIENTIFIC Obtryx product through television, print and internet advertising and by sending sales representatives throughout the United States and to the State of Alabama to promote the sale of the BOSTON SCIENTIFIC Obtryx product, including that which was implanted in the Plaintiff.
16. Defendants at all times material hereto packaged the BOSTON SCIENTIFIC Obtryx product, including that which was implanted in the Plaintiff.
17. Defendants at all times material hereto labeled the BOSTON SCIENTIFIC Obtryx product by placing its name on the outside of the BOSTON SCIENTIFIC Obtryx's packaging.
18. Defendants at all times material hereto, sold the BOSTON SCIENTIFIC Obtryx product throughout the United States, including the State of Alabama.

19. Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act ("Section 510(k)") allows the marketing of medical devices of the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 29, 1976.

20. A predicate device is one that the Food and Drug Administration ("FDA") has placed into one of three classification categories and "cleared" for marketing. These regulatory classification categories include Class I, Class II, and Class III medical devices.

21. Under Section 510(k), a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a predicate device.

22. Under Section 510(k), no formal review for safety or efficacy is required.

23. The BOSTON SCIENTIFIC Obtryx product manufactured by Defendants is considered a Class II medical device under the FDA's medical device regulatory classification system.

24. Defendant sought and obtained the FDA's approval to market the BOSTON SCIENTIFIC Obtryx Exact System product under Section 510(k).

25. Defendants were, or should have been aware, of the dangers inherent in the BOSTON SCIENTIFIC Obtryx product generally, notwithstanding the fact that this product was "cleared" for sale by the FDA.

26. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Product has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Ms. Plyler, making them defective under the law.

27. The specific nature of the Product's defects includes, but is not limited to, the following:

a. the use of polypropylene material in the Product and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

e. the propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

f. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

g. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

28. The Product is also defective due to Defendants' failure to adequately warn or instruct Ms. Plyler and/or her health care providers of subjects including, but not limited to, the following:

a. the Product's propensities to contract, retract, and/or shrink inside the body;

b. the Product's propensities for degradation, fragmentation and/or creep;

c. the Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Product;

f. the risk of chronic infections resulting from the Product;

g. the risk of permanent vaginal or pelvic scarring as a result of the Product;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i. the need for corrective or revision surgery to adjust or remove the Product;

j. the severity of complications that could arise as a result of implantation of the Product;

k. the hazards associated with the Product;

l. the Product's defects described herein;

m. treatment of stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n. treatment of stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o. treatment of stress urinary incontinence with the Product makes future surgical repair more difficult than feasible available alternatives;

p. use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

29. Defendants had underreported information about the propensity of the Product to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Product through various means and media.

30. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.

31. Defendants failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Product exists.

32. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as do the Product.

CAUSES OF ACTION AGAINST ALL DEFENDANTS

COUNT I
NEGLIGENCE

33. Plaintiff incorporates by reference paragraph 1-32 of this Complaint as if fully set forth herein.

34. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the BOSTON SCIENTIFIC Obtryx.

35. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the BOSTON SCIENTIFIC Obtryx.

36. As a direct and proximate result of Defendants' negligence, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

37. Plaintiff incorporates by reference paragraphs 1-32 of this Complaint as if fully set forth herein.

38. The BOSTON SCIENTIFIC Obtryx product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law with respect to its design.

39. As a direct and proximate result of the BOSTON SCIENTIFIC Obtryx's aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligation for medical services and expenses, lost income, and other damages.
40. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

Wherefore, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT III
STRICT PRODUCT LIABILITY – MANUFACTURING DEFECT

41. Plaintiff incorporate by reference paragraphs 1-32 of this Complaint as if fully set forth herein.
42. The BOSTON SCIENTIFIC Obtryx product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.
43. As a direct and proximate result of the BOSTON SCIENTIFIC Obtryx's aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

Wherefore, Plaintiff demands judgment against the Defendants for compensatory, treble

and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT IV
STRICT LIABILITY – FAILURE TO WARN

44. Plaintiff incorporates by reference paragraphs 1-32 of this Complaint as if fully set forth herein.

45. The BOSTON SCIENTIFIC Obtryx product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law due to its lack of appropriate necessary warnings.

46. As a direct and proximate result of the BOSTON SCIENTIFIC Obtryx's aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT V
BREACH OF EXPRESS WARRANTY

47. Plaintiff incorporates by reference paragraph 1-32 of this Complaint as if fully set forth herein.

48. Defendants made assurances to the general public, hospitals and health care professionals that the BOSTON SCIENTIFIC Obtryx was safe and reasonably fit for its intended purpose.
49. Plaintiff and/or her health care provider chose the BOSTON SCIENTIFIC Obtryx based upon Defendants' warranties and representations regarding the safety and fitness of the BOSTON SCIENTIFIC Obtryx.
50. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the BOSTON SCIENTIFIC Obtryx was safe, merchantable, and reasonably fit for its intended purpose.
51. Defendants breached these express warranties because the BOSTON SCIENTIFIC Obtryx implanted in Plaintiff was unreasonably dangerous and defective and not as Defendants represented.
52. Defendants' breaches of its express warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.
53. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT VI

BREACH OF IMPLIED WARRANTY

54. Plaintiff incorporates by reference paragraph 1-32 of this Complaint as if fully set forth herein.

55. Defendants impliedly warranted that the BOSTON SCIENTIFIC Obtryx was merchantable and was fit for the ordinary purpose for which it was intended.

56. When the BOSTON SCIENTIFIC Obtryx was implanted in Plaintiff to treat her for Stress Urinary Incontinence, Menorrhagia and other symptoms, it was being used for the ordinary purposes for which it was intended.

57. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the BOSTON SCIENTIFIC Obtryx implanted in her.

58. Defendants breached these implied warranties of merchantability because the BOSTON SCIENTIFIC Obtryx product implanted in the Plaintiff was neither merchantable nor suited for its intended use as warranted.

59. Defendants' breaches of its implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

60. As a direct and proximate result of Defendant's breaches of the aforementioned implied warranties, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble

and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

Plaintiffs Demand a Jury Trial on all issues.

Dated: March 8, 2019,

RESPECTFULLY SUBMITTED,

/s/ William L. Bross
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